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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,277	10/23/2003	Loran James Paprocki	14709	7141

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

88

Office Action Summary	Application No. 10/692,277	Applicant(s) PAPROCKI, LORAN JAMES	
	Examiner Kathleen Sonnett	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
 4a) Of the above claim(s) 14-19 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-13 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/29/04, 8/3/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-13, drawn to a tract plug apparatus, classified in class 606, subclass 213.
 - II. Claims 13-19, drawn to a method of using a tract plug, classified in class 128, subclass 898.
2. The inventions are distinct, each from the other because of the following reasons: Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process as it can be used to plug a drain hole or other non-biological product. Also, the tract plug, as claimed in claim 1 can be used as a stent to hold open an artery.
3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Sean Solberg on 4/18/2006 a provisional election was made without traverse to prosecute the invention of the apparatus, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office

Art Unit: 3731

action. Claims 14-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1, 2, and 6 – 13** are rejected under 35 U.S.C. 102(b) as being anticipated by Janzen et al. (U.S. 5,948,425). Janzen et al. discloses a tract plug comprising segments of biosorbable material wherein the segments are linked (Fig. 12c and col. 7 lines 12-21). The links are severably linked as the plug can be cut along the line where the two segments are joined.

7. Regarding claims 6-8, the segments comprise fibers and the linking is accomplished by contact between the fibers of one segment with the fibers of another segment. The contact is created by compression, as the segments must make contact in order to be linked together. The biosorbable material is collagen (col. 7 lines 12-21).

8. Regarding claim 9, Janzen et al. discloses a device for inserting the tract plug into a tract (see Fig. 17).

9. Regarding claim 10, Janzen et al. discloses a generally elongated body comprising units made of biocompatible material, wherein the units are separably joined so that the length of the body may be selected initially by joining a selected number of

Art Unit: 3731

units to form the body. The plug can be manufactured to include a selected number of units, which will determine its length. The length of the body can be changed after it has been formed by separating one or more of the joined units. In this case, the surgeon can separate the joined units by cutting them anywhere, including at their linkage point, as Janzen et al. discloses that material of the plug remaining outside of the hole can be cut off (col.9 lines 45-52).

10. Regarding claim 11, see the abstract.

11. Regarding claim 12, the hemostasis promoting material is collagen (col. 2 lines 21-26).

12. Regarding claim 13, the contacting surfaces and the fibers that form the interface join the units.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. **Claims 3-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Janzen et al. in view of Valentine et al. (U.S. 5,387,206). Janzen et al. discloses the invention substantially as stated above, but fails to disclose a line of weakness between the segments that comprises perforations.

Art Unit: 3731

15. However, Valentine et al. discloses that it is old and well known in the art to include a medical sponge with perforations ("34" Fig. 4) formed on one end of the medical sponge. The perforations form a line of weakness and impart increased flexibility allowing easier insertion into body cavities or surgical openings with limited access (col. 2 line 55-col. 3 line 4). The increased flexibility of the medical sponge also decreases the chances of tissue damage during insertion. Valentine et al. suggests that the lines of weakness formed by perforations can be used in a variety of medical sponges (col. 4 lines 39-44). Forming lines of weakness between the segments disclosed by Janzen et al. would increase the flexibility of the plug. Regarding claim 5, the lines of perforations disclosed by Valentine et al. are generally traverse to the length. If the segments are separated from each other along the line of weakness, the length of the plug is shortened. Therefore, it would have been obvious to one of ordinary skill in the art to include a line of weakness comprising perforations between the segments disclosed by Janzen et al. as made obvious by Valentine et al. in order to increase the flexibility of the plug thereby decreasing the likelihood of tissue damage during insertion of the plug.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KCS


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER

4/28/06